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(54) **Device for haemostatic treatment following catheterization.**

(57) The invention relates to a device for haemostatic treatment following catheterization. It comprises an elongated tubular penetration member with at least one longitudinal channel which ends close to an external end in a connecting piece, a pressure gauge, connecting means for connecting the connecting piece to the pressure gauge, a supply means for a haemostatic pharmacon comprising a reservoir for the collagen and a supply line connected to it which terminates in a connecting member. Close to the external end the penetration member is provided with an associated connecting member in which a longitudinal channel of the penetration member ends. The invention relates to and also provides a penetration member to be used with a device as described.

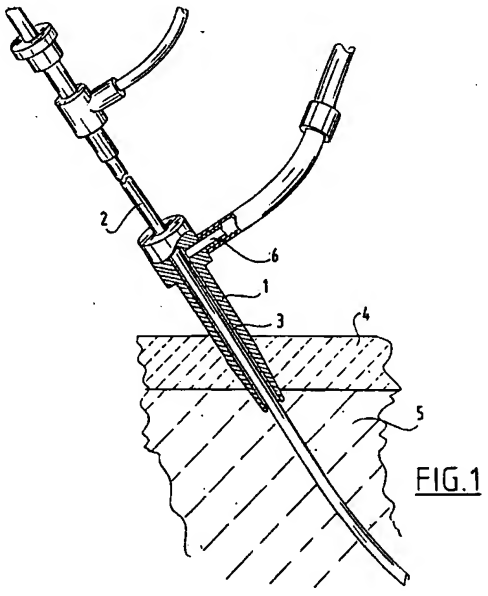

FIG.1

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The invention relates to a device used to carry out haemostatic treatment following catheterization.

Following catheterization and after removal of the catheter introduction member inserted through the skin and the vascular wall, a puncture wound will remain which is at times difficult to close and may continue to bleed for a long time. It is a well-known procedure to apply a plug of haemostatic pharmacon up against the vascular wall in order to stem the flow of blood. Correct positioning of the collagen plug is difficult to achieve however.

The object of the invention is to provide a device with which such treatment can be simplified.

According to the invention this is achieved with the device as characterised in claim 1.

Following catheterization, the penetration member which has first been inserted through the skin and the vascular wall, is withdrawn gradually whilst observing the pressure gauge connected to the connecting piece. When the pressure gauge indicates a falling pressure, it is an indication that the end of the penetration member has been drawn back to a position right inside or just outside the vascular wall. By way of the supply means, which is connected to a longitudinal channel of the penetration member by means of the attached connecting pieces, a haemostatic pharmacon is deposited in exactly the right position. Thus it is ensured that the haemostatic pharmacon will not end up in the blood vessel itself which could result in a serious complication for the patient.

The device according to the invention can be manufactured as characterised in claim 2. As the phase during which the haemostatic pharmacon is supplied follows pressure measurement, one and the same channel can be used for both the pressure measurement and the supply of the haemostatic pharmacon.

The invention relates to and also provides a penetration member which is apparently designed for a device according to the invention as described above.

This member is preferably manufactured as characterised in claim 4. Consequently, exact positioning of the penetration member and more in particular of the opening through which the haemostatic pharmacon will be ejected in or close to the vascular wall can be effected. The haemostatic pharmacon will always be ejected in a position a little further back from where the pressure is measured so that one can be assured that this haemostatic pharmacon will be deposited in the right place.

The invention will be explained in the following description with reference to the attached drawings.

Figure 1 shows schematically an introduction member for an angiographic catheter in the position of use.

Figure 2 shows more or less schematically a device according to the invention in the position of use.

Figure 3 represents a graph of an example of the pressure changes as measured during the application of the invention.

Figure 4 illustrates another embodiment of a device according to the invention.

Figures 5 and 6 show sections of two other embodiments of a device according to the invention.

Figures 7, 8 and 9 show schematically three further embodiments.

Figure 1 illustrates an introduction member 1 which is introduced by means of known appliances, not shown in fig. 1, through the skin and the wall 4 of a blood vessel. The introduction member 1 comprises a longitudinal channel 3 through which a catheter 2 can be introduced which consequently will end up in the lumen 5 of the blood vessel and which can be advanced via the blood vessel to the desired, to be treated or to be investigated area.

The introduction member is of a known type and is, in this case, fitted with a side connection 6, connected with the longitudinal channel 3.

Fig. 2 shows a device according to the invention. It comprises a penetration member 10, which can for instance be an introduction member such as the introduction member shown in fig. 1. The penetration member 10 is fitted with a longitudinal channel 11 which, close to an external end remaining outside the body of the patient, ends in a connecting piece 12. The connecting piece 12 is, with the aid of connecting means 13, in this example of the embodiment made of a tube, connected with a pressure gauge 14 which consequently can indicate the pressure in the channel 11.

The device according to the invention comprises furthermore a supply means 15 for a haemostatic pharmacon, which supply means 15 comprises a reservoir 17 for the haemostatic pharmacon 16. The supply means 15 has been made in the form of a hypodermic syringe and is fitted at its outlet with a connecting member 18 which is associated with a connecting member 19 at the external end of the penetration member 10. This connecting member 19 is connected to a longitudinal channel which in this case is the same longitudinal channel 11 to which the connecting piece 12 is connected.

The device can be used in the following manner.

Following catheterization and after removal of the catheter, the penetration member 10 is introduced through the vascular wall 4. In case the introduction member already used for introducing the catheter is used as penetration member, it obviously will not be necessary to introduce it once again. With the aid of the connecting means 13,

the pressure gauge 14 is connected to the connecting piece 12. In the situation wherein the penetration member 10 extends into the lumen 5 of the blood vessel, the pressure gauge will indicate the pressure prevailing in the lumen 5 of the blood vessel 4. When the penetration member 10 is withdrawn slowly, the pressure indicated by the pressure gauge 14 will fall away gradually as soon as the internal end of the penetration member is withdrawn from the lumen 5 of the blood vessel.

This has been illustrated schematically in fig. 3. This graph indicates time on the horizontal axis and pressure on the vertical axis. As long as the penetration member extends into the lumen 5 of the blood vessel, a pressure measurement indicated with 22 is obtained from inside the lumen of the blood vessel. On withdrawal the internal end of the penetration member will pass the opening 20 in the wall 4 of the blood vessel. This opening 20 will contract slightly due to which the pressure measurement will fall off as indicated in fig. 3 with the number 23. As soon as the penetration member has been withdrawn sufficiently, which can be read on the pressure gauge 14, the supply means 15 will be activated and the haemostatic pharmacon 16 will be ejected through the longitudinal channel 11, thus closing the puncture wound.

It should be noted that in the drawings the vascular wall 4 has been drawn relatively thick. For a clear understanding of the invention one can however look upon it as being the vascular wall itself together with the adjoining layers of tissue. The haemostatic pharmacon does not need to be conveyed to inside the wall of the blood vessel itself but can be conveyed to the adjoining layers of tissue.

The device 25 in fig. 4 has been made slightly different to the device shown in fig. 2. An insertion piece 27 is inserted into the penetration member 26 when, with the aid of the pressure gauge 32, it has been established that the penetration member has been withdrawn sufficiently far. The pressure gauge 32 is, by way of schematically indicated connecting means, connected to the connecting piece 33 which is connected directly to the central longitudinal channel 30 of the penetration member 26. The insertion piece 27 has a tubular shape and comprises its own longitudinal channel 31 which ends, close to the external end, in a connecting member situated inside the connecting means 28 by way of which the supply means 29 is connected to the insertion piece 27.

Fig. 5 shows the bottommost or internal end of a means 25 of the type as shown in fig. 4 with a differently shaped insertion piece. In fig. 5 the insertion piece 34 comprises a side hole 35, so that the haemostatic pharmacon 36 is ejected sideways. Thus the risk that the haemostatic pharmacon will enter the blood vessel itself via the opening in the vascular wall, which could entail serious complications for the patient, is minimized.

Fig. 6 shows a derived form wherein the insertion piece 37 comprises a number of side holes 38 for the purpose of ejecting the haemostatic pharmacon 39 sideways around the entire circumference.

In the case of the penetration member 42 as shown in fig. 7 the connection member 45 and the connection piece 43 are connected to separate channels, 46 and 44 respectively, inside the penetration member 42. Because of this, pressure measurement with the aid of the pressure gauge connected with the connecting piece 43 can continue, whilst the haemostatic pharmacon is ejected via the connection member 45 and the longitudinal channel 46. The pressure measurement can thus give an indication as to the progress of the supply of the haemostatic pharmacon.

In fig. 8 a somewhat altered embodiment is shown. In this case the penetration member 50 also comprises separate channels 51 and 52 connected with the connecting piece and the connecting member respectively. The internal end 53 of the channel 52 ends at some distance before the internal end of the channel 51. Consequently the haemostatic pharmacon is always ejected at a somewhat greater distance from the opening in the vascular wall, so that careful positioning is possible. The penetration member 50 only needs to be withdrawn to the point where the pressure gauge indicates a reduction in pressure. This is an indication of passing the puncture in the vascular wall. When subsequently the supply means is activated, the haemostatic pharmacon will be deposited in the right place.

Fig. 9 shows an embodiment developed to an even greater degree. The penetration member 54 is essentially closed off at its bottommost or internal end. The channel 55 connected with the connecting piece, ends in an opening 56 at the bottom of the penetration member 54. The channel 57 connected to the connecting member ends in a side hole 58.

Claims

1. Device for haemostatic treatment following catheterization, comprising an elongated tubular penetration member with at least one longitudinal channel which ends close to an external end in a connecting piece, a pressure gauge, connecting means for connecting the connecting piece to the pressure gauge, a supply means for a haemostatic pharmacon comprising a reservoir for the haemostatic pharmacon and a supply line connected to it

which ends in a connecting member and wherein the penetration member, close to the external end, is provided with an associated connecting member inside of which a longitudinal channel of the penetration member terminates.

2. Device as claimed in claim 1, wherein the connecting member and the connecting piece of the penetration member are connected with one and the same central channel of the latter.

3. Penetration member apparently designed for a device as claimed in claim 1.

4. Penetration member as claimed in claim 3, wherein the connecting member and the connecting piece are connected with separate channels and wherein the internal end of the channel connected to the connecting member is situated at a distance in front of the internal end of the channel connected to the connecting piece.

5. Penetration member as claimed in claim 3, wherein the channel connected with the connecting member has at least one side hole at the internal end.

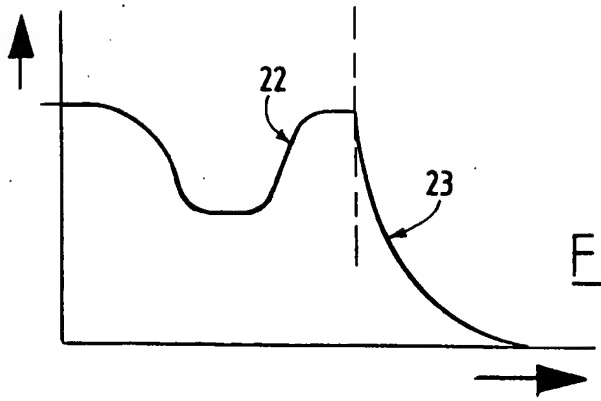

FIG.3

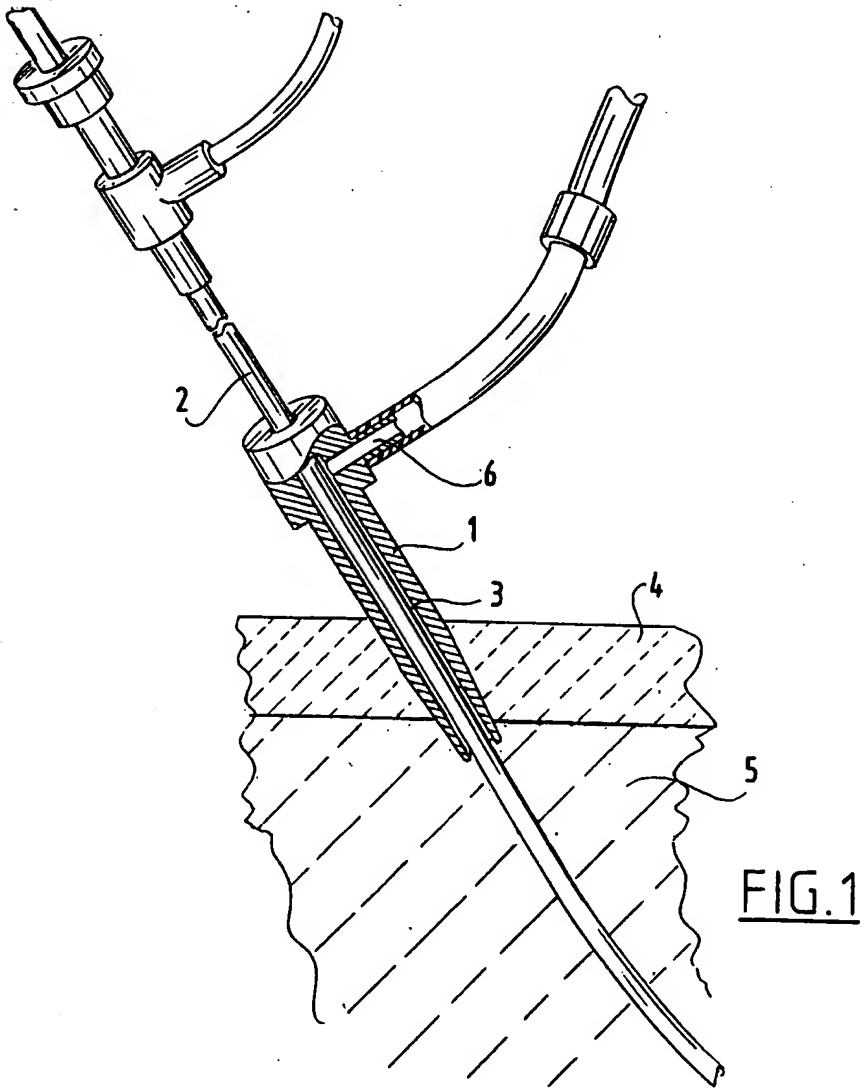

FIG.1

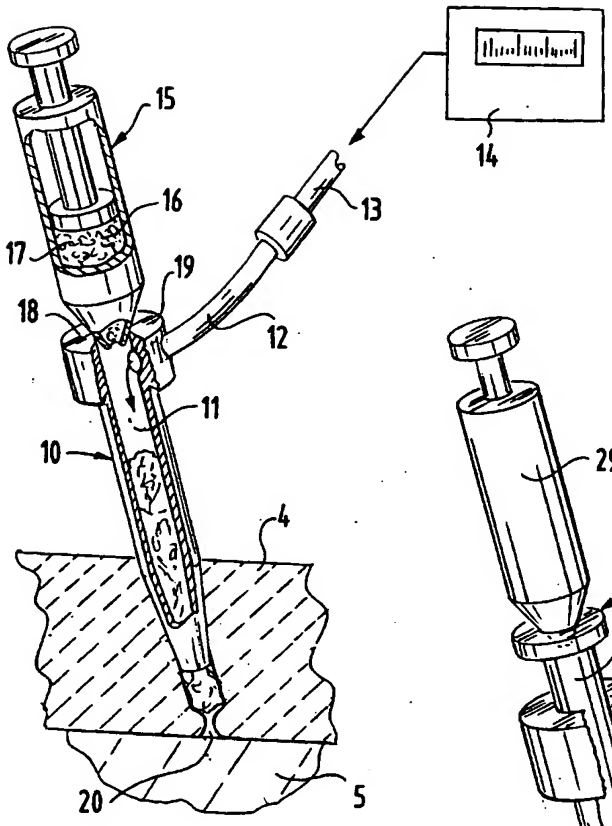

FIG.2

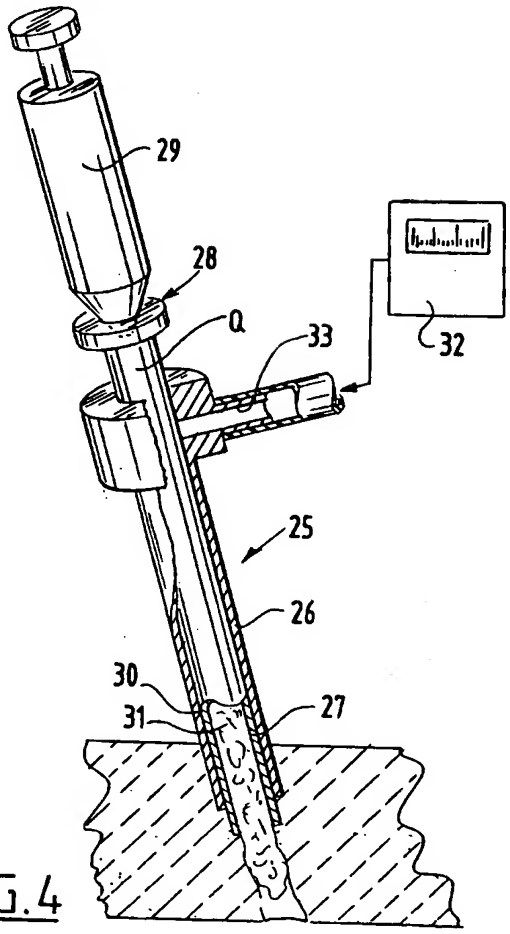

FIG.4

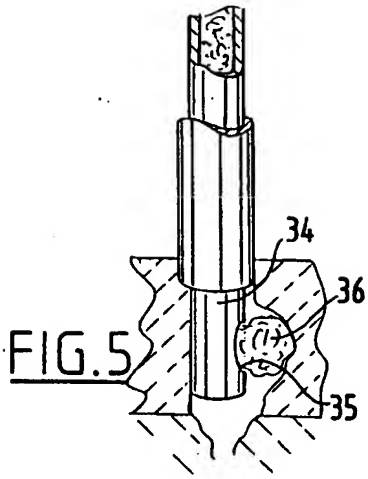

FIG.5

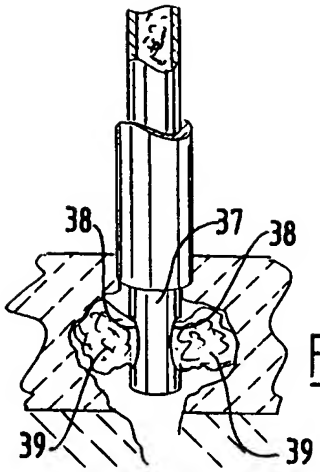

FIG.6

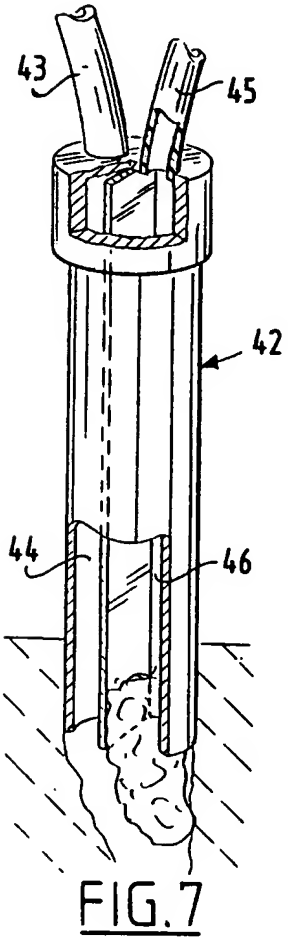

FIG.7

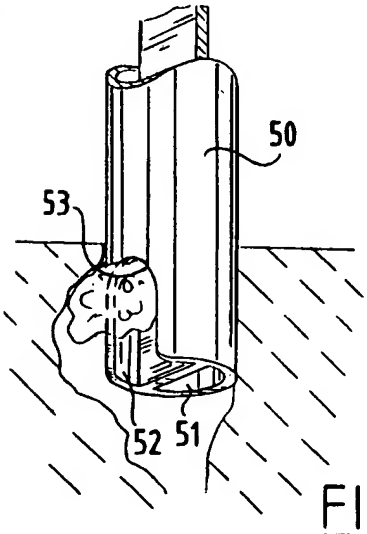

FIG.8

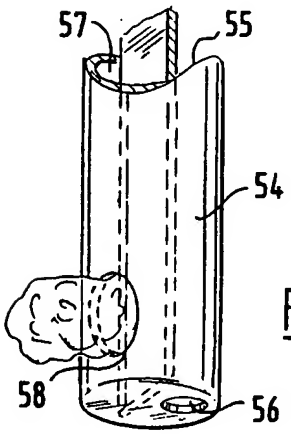

FIG.9

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EUROPEAN SEARCH REPORT

Application Number
EP 94 20 2384

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	EP-A-0 241 038 (TERUMO) * column 6, line 19; figure 5 * * column 6, line 28; figure 1A *	1-5	A61B17/00
X	WO-A-93 08746 (KENSEY NASH) * page 16, paragraph 1; figure 12 *	3-5	
X A	EP-A-0 482 350 (DATASCOPE) * abstract; figure 2 *	3 2	
X	EP-A-0 556 564 (BARD) * abstract; figure 2 * & CA-A-2 087 906 (BARD)	3	
A	WO-A-92 05740 (QUINTON)		
A	EP-A-0 493 810 (NOVOSTE)		

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	10 November 1994	Barton, S

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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